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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,577	10/23/2003	Lilip Lau	PARCR 65971	1087
24201	7590	09/01/2005	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/693,577	Applicant(s) LAU ET AL.	
	Examiner Samuel G. Gilbert	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-63 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-63 and 65-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/27/05; 4/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 4/28/2005 and 6/27/2005 have been considered.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Every effort should be made to make the title unique with regards to the applicant's related applications.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "self-sizing", "self-attaching", self-tensioning", "self-adhering", and "self-expanding".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 54-63 and 65-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims include a positive recitation of the heart and human body parts are not patentable subject matter.

The applicant may want to use "adapted to" language such as;

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- in claim 54, "extending circumferentially on an outer surface of the heart" could be written as – are adapted to extend circumferentially around an outer surface of the heart--.
- In claim 55, "elements extend circumferentially" could be written --elements are adapted to extend--. Appropriate correction in all the claims is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the claim "self-expanding", is considered to be new-matter and not described in the originally filed specification as required.

Claim Objections

Applicant is advised that should any of claims 55-58 be found allowable, the remainder of claims 55-58 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close

in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The terms self-sizing, self-attaching, self-tensioning, and self-adhering set forth a functional property of the claimed device. In the applicant's arguments of 6/2/2005 the applicant sets forth that the property of the structure required to perform these functions were all the same, the elasticity of the structure. Because each of these claims require only the same structure they would be improper duplicates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-63 and 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (6,360,749) in view of Lau et al (6,517,570).

Jayaraman teaches a medical device, figures 6B, 7B, 7C, 8A, 8B-12 and 14 for treating the heart including elastic bands but does not teach the material including a plurality of hinge elements. Jayaraman does set forth that stent graft materials may be used. Lau et al. sets forth a plurality of embodiments of stent graft material formed by a plurality of hinge elements, the embodiments of figures 3, 4, 5, 6, 8, 10, 11, 12, teach non-overlapping hinge elements. Lau et al sets forth that the hinged elements provide

the advantage of being foldable to be delivered intraluminally, kink-resistant and self-expanding. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the stent graft material taught by Lau et al. to be used for the stent graft material set forth to provide the benefits as described above to the cardiac treatment device of Jayaraman. Lau et al. further teaches the use of non-overlapping hinge elements with torsion bars provide the advantage of allowing the device to be formed from a flat sheet and having torsional balance by spreading the load when the material is folded into a small diameter, column 12 lines 1-8.

Claim 55 - the hinge elements of Lau et al are "self-sizing" and the cardiac device of Jayaraman is adapted to extend circumferentially around the heart.

Claim 56 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are elastic which provide the capability of being "self-attaching". The examiner sets forth the following example; if the unstressed circumference of Jayaraman is smaller than the smallest circumference of the patients heart on which it is to be used then the jacket must be expanded to be placed on the heart the elasticity of the device would urge the device back to its unstressed condition which would make the device "self-attaching".

Claim 57 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are inherently "self-tensioning".

Claim 58 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are elastic which provide the capability of being "self-adhering". The examiner sets forth the following example; if the unstressed

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circumference of Jayaraman is smaller than the smallest circumference of the patients heart on which it is to be used then the jacket must be expanded to be placed on the heart the elasticity of the device would urge the device back to its unstressed condition which would make the device "self-adhering".

Claim 59 – the compressive force of Jayaraman would be a function of the starting size of the jacket and the size of the heart on which it is used. It is the examiner's position that any sized cardiac device taught by Jayaraman would generate a compressive force if the maximum circumference of the heart is smaller than the starting circumference of the cardiac jacket.

Claims 60 and 61 – the compliance is an inherent feature of the hinge elements set forth in figures 1A-1E of Lau et al.

Claim 62 – Jayaraman teaches strips that extend circumferentially around the heart.

Claim 63 – the material of Lau et al. provide a compressible to a low profile. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 65 – the hinge elements of Lau et al are "self-expanding" see the title of Lau et al.

Claim 66 – Lau et al teaches the use of Nitinol, column 12 lines 31 and 32.

Claim 67 – the Nitinol hinge elements of Lau et al inherently have a deformed shape and a recovered shape.

Claim 68 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 69 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 70 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,702,732. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,682,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,663,558. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,595,912. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-74 of copending Application No. 10/865,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 54-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-62 of copending Application No. 10/314,696. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 6/2/2005 have been fully considered but they are not persuasive.

The applicant argues that the specification has support for all the following terms except "self-expanding". The examiner agrees if the elasticity of the bands forms the basis for the support, however the specification still fails to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "self-sizing", "self-attaching", self-tensioning", "self-adhering", and "self-expanding".

The applicant appears to have canceled claim 64 instead of 65 therefore the arguments regarding claim 65 are mute.

Regarding the arguments directed to the rejection under 35 USC 103 Jayaraman in view of Lau et al the applicant argues

- a person having ordinary skill in the art would understand that one device could not be used as a substitute for the other.

In response the examiner agrees that one could not substitute either of the devices for the other and the examiner has made no such rejection or substitution, therefore the argument is mute.

- A person of ordinary skill in the art would not look to Lau et al under any circumstances to solve a completely different problem.

In response it is the examiner's position that Jayaraman provide the motivation to look to stent graft material by specifically teaching that the bands can be made from stent graft material, at least in column 5 line 20.

- The applicant argues that Jayaraman does not teach hinge elements.

In response the examiner agrees, however the rejection in question is based on Jayaraman in view of Lau et al. Therefore the argument is mute.

- The applicant argues Jayaraman does not teach hinge elements configured to be delivered minimally invasively,

Again, in response the examiner agrees, however the rejection in question is based on Jayaraman in view of Lau et al. Therefore the argument is mute.

- the applicant argues that Jayaraman states the bands can also be made from stent graft material and that such a statement is insufficient motivation to combine Jayaraman with Lau et al.

In response the examiner agrees and would like to point out that Lau et al. sets forth the motivation used by the examiner. The motivation set forth above and now restated, Lau et al sets forth that the hinged elements provide the advantage of being foldable to be delivered intraluminally, kink-resistant and self-expanding.

- The applicant further argues that Jayaraman sets forth an apparatus that can be placed through minimally invasive surgery,

but does not disclose how or by what structure would be used to deliver the device through minimally invasive surgery.

In response, the applicant's claims are not directed to a method of implanting the device and only require a device that is configured to be delivered minimally invasively. The applicant points out that Jayaraman teaches that the bands are retractable or collapsible column 12 lines 52-60 of Jayaraman, therefore it is the examiner's position that the device is configured to be delivered minimally invasively.

- The applicant argues that Lau et al does not teach hinge elements extending circumferentially on the outer surface of the heart.
- In response the examiner agrees, however the rejection in question is based on Jayaraman in view of Lau et al. Therefore the argument is mute.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

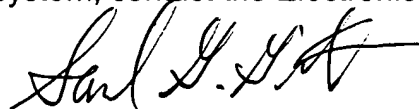
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3736

SGG
8/28/2005